# SECTION 5 - 510(k) Summary

## ELITech Clinical Systems CREATININE PAP SL

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| **Introduction** | According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.<br><br>The assigned 510(k) number is: **K103376** |
| **Submitter** | SEPPIM S.A.S. |
| **Address** | Zone Industrielle, 61500 SEES, FRANCE |
| **Phone number** | + 33 (0)2 33 81 21 00 |
| **Fax number** | + 33 (0)2 33 28 77 51 |
| **Contact** | Valérie GOURDON (Email: v.gourdon@elitechgroup.com) |
| **Date of Preparation** | November 8th, 2010 |

**Device names**

REAGENT

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|---|---|
| Trade/proprietary Name: | **ELITech Clinical Systems CREATININE PAP SL** |
| Common or Usual Name: | Creatinine, **"CREATININE PAP SL"** |
| Device Class | Class II |
| Classification name | Creatinine test system (Sec.862.1225) |
| Product code | JFY– Enzymatic method, Creatinine |

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| **Predicate device** | Roche Diagnostics Creatinine plus ver.2 (K024098) |
| **Device description** | The device for this submission is available as kit only. It consists of 2 reagents, "R1" and "R2".<br>Reagent R1 contains: MOPS buffer (pH 7.50), EHSPT (N-Ethyl-N-2(-Hydroxy-3-Sulfopropyl)-*m*-Toluidine), Creatinase (microoganism), Sarcosine oxidase (microoganism), Ascorbate oxidase (vegetal).<br>Reagent R2 contains: MOPS buffer (pH 7.50), Amino-4-antipyrine (4-AAP), Creatininase (bacterial), Peroxidase (horseradish), and Sodium azide. |
| **Intended Use** | ELITech Clinical Systems CREATININE PAP SL is intended for the quantitative *in vitro* diagnostic determination of CREATININE in human serum and plasma on Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings. |
| **Indication for use** | ELITech Clinical Systems CREATININE PAP SL is intended to measure creatinine in human serum and plasma. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis. |

**Comparison to Predicate device**

| | ELITech Clinical Systems Device<br>CREATININE PAP SL | Predicate device<br>(Roche Diagnostics Creatinine plus ver.2) |
|---|---|---|
| Intended use | Intended for the quantitative *in vitro* diagnostic determination of creatinine in human serum or plasma on Vital Scientific Selectra/Flexor analyzers.<br>It is not intended for use in Point of Care settings. | For *in vitro* diagnostic use in the quantitative determination of creatinine in serum, plasma and urine on the cobas c111 system. |
| Indication for Use | Creatinine measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis. | Creatinine measurements are used in the diagnosis and treatment renal diseases, in monitoring renal dialysis and as a calculation basis for measuring other urine analytes. |
| Assay protocol | Enzymatic colorimetric test | Enzymatic colorimetric test |
| Composition | Reagent R1:<br>MOPS buffer (pH 7.50)<br>EHSPT 0.4 mmol/L ;<br>Creatinase ≥ 10 000 U/L ;<br>Sarcosine oxidase ≥ 3 250 U/L ;<br>Ascorbate oxidase ≥ 1 000 U/L ;<br><br>Reagent R2:<br>MOPS buffer (pH 7.50)<br>4-Aminoantipyrine 2.95 mmol/L ;<br>Creatininase ≥ 150 000 U/L ;<br>Peroxidase ≥ 4 000 U/L ;<br>Sodium azide < 0.1 %; | Reagent R1:<br>TAPS buffer 30 mmol/L ;<br>Creatinase ≥ 332 µkat/L ;<br>Sarcosine oxidase ≥ 132 µkat/L ;<br>Ascorbate oxidase ≥ 33 µkat/L ;<br>HITB 1.2 g/L ;<br>Detergents<br>Preservative<br><br>Reagent R2:<br>TAPS buffer 50 mmol/L ;<br>Creatininase ≥ 498 µkat/L ;<br>4-Aminophenazone 0.5 g/L ;<br>Peroxidase ≥ 16.6 µkat/L ;<br>Potassium hexacyanoferrate(II) 60mg/L;<br>Detergents<br>Preservative |
| Appearance of reagents | Liquid form, ready to use | Same |
| Sample type | Serum<br>Plasma | Serum<br>Plasma<br>Urine |
| Reagent storage | Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label. | Stored at 2-8 °C.<br>Reagents are stable until the expiry date stated on the label. |
| Expected values | Serum/plasma:<br>Adults :<br>Females 0.55 – 1.02 mg/dL<br>Males 0.72 – 1.18 mg/dL | Serum/plasma:<br>Adults :<br>Females 0.51 – 0.95 mg/dL<br>Males 0.67 – 1.17 mg/dL<br>Children:<br>Neonates(premat.) 0.33-0.98 mg/dL<br>Neonates(full term) 0.31-0.88 mg/dL<br>2-12 m 0.16-0.39 mg/dL<br>1-< 3 y 0.18-0.35 mg/dL<br>3-< 5 y 0.26-0.42 mg/dL<br>5-< 7 y 0.29-0.47 mg/dL<br>7-< 9 y 0.34-0.53 mg/dL<br>9-< 11 y 0.33-0.64 mg/dL<br>11-< 13 y 0.44-0.68 mg/dL |

| | ELITech Clinical Systems Device<br>CREATININE PAP SL | Predicate device<br>(Roche Diagnostics Creatinine plus ver.2) |
|---|---|---|
| | | 13-< 15 y 0.46-0.77 mg/dL |
| Instrument | Vital Scientific SELECTRA JUNIOR | Cobas c111 |
| Measuring range | 0.28 – 22.30 mg/dL | 0.06 – 30.5 mg/dL |
| Limit of detection (LoD) | 0.006 mg/dL | Serum/plasma: 0.06 mg/dL |
| Limit of quantification (LoQ) | 0.28 mg/dL | |
| Precision | **Within run**<br>Level 0.59 mg/dL CV=1.3%<br>Level 1.62 mg/dL CV=0.8%<br>Level 6.93 mg/dL CV=1.4%<br><br>**Total**<br>Level 0.59 mg/dL CV=3.2%<br>Level 1.62 mg/dL CV=1.6%<br>Level 6.93 mg/dL CV=2.8% | Serum/plasma:<br>**Within run**<br>Level 0.97 mg/dL CV=2.29%<br>Level 3.95 mg/dL CV=1.16%<br>Level 0.77 mg/dL CV=2.86%<br>Level 12.7 mg/dL CV=1.26%<br>**Total**<br>Level 0.97 mg/dL CV=2.35%<br>Level 3.95 mg/dL CV=0.91%<br>Level 0.75 mg/dL CV=1.87%<br>Level 13.2 mg/dL CV=0.60% |
| Method comparison | y=1.045x – 0.01 mg/dL<br>r= 0.999<br>range: 0.30 to 20.30 mg/dL | Serum/plasma:<br>y=1.006x – 1.11899 µmol/L (0.013 mg/dL)<br>r= 0.9998<br>range: 45.9 to 1674 µmol/L (0.52 to 18.9 mg/dL) |
| Limitations | **Hemoglobin:** No significant interference up to 500 mg/dL.<br>**Triglycerides:** No significant interference up to 3198 mg/dL .<br>**Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL.<br>**Conjugated bilirubin:** No significant interference up 14.8 mg/dL.<br>**Uric acid:** No significant interference up to 24 mg/dL.<br>**Glucose:** No significant interference up to 550 mg/dL.<br>**Ascorbic acid:** No significant interference up to 20 mg/dL.<br>**Methyl-dopa:** Induce falsely low results at therapeutic concentrations.<br>**L-dopa:** Induce falsely low results at therapeutic concentrations.<br>**Calcium dobesilate:** Induce falsely low results at therapeutic concentrations.<br>**Creatine:** Positive bias from 5 mg/dL. | **Hemoglobin:** No significant interference up to an H Index of 800 (approximate 800 mg/dL).<br>**Lipemia (Intralipid):** No significant influence up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.<br>**Icterus:** No significant influence up to I Index of 20 (approximate conjugated and unconjugated bilirubin concentration of 20 mg/dL (342 µmol/L)).<br>Ascorbic acid: < 300 mg/L does not interfere.<br>**Drugs:** No interference was found at therapeutic concentrations using common drug panels.<br>Exceptions: Levodopa and calcium dobesilate cause artificially low creatinine levels at the tested drug level<br>**Other:** In very rare cases monoclonal gammopathy can lead to incorrect results.<br>No significant interference up to a creatine level of 20 mg/dL. |
| Calibration Frequency | 14 days | Each lot and as required following quality control procedures. |

| | ELITech Clinical Systems Device<br>CREATININE PAP SL | Predicate device<br>(Roche Diagnostics Creatinine plus ver.2) |
|---|---|---|
| On board stability | refrigerated area : 28 days | refrigerated area: 4 weeks |
| Calibrator | Recommended calibration material (not included):<br>ELITech Clinical Systems ELICAL 2 | Recommended calibration material (not included):<br>Roche Calibrator f.a.s. |
| Controls | Recommended quality control material (not included):<br>ELITech Clinical Systems ELITROL I (Normal control)<br>ELITech Clinical Systems ELITROL II (Pathologic control) | Recommended quality control material (not included):<br>Roche Precinorm U<br>Roche Precipath U |

**Device names**

CALIBRATOR :

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|---|---|
| Trade/proprietary Name: | **ELITech Clinical Systems ELICAL 2** |
| Common or Usual Name: | Calibrator, multi-analyte mixture, "**ELICAL 2**" |
| Device Class | Class II |
| Classification name | Calibrator (21 CFR 862.1150) |
| Product code | JIX- Calibrator, multi-analyte mixture |

**Predicate device**

Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) (K033501)

**Device description**

ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.
ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

**Intended Use**

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on Vital Scientific Selectra Junior Analyzer and Vital Scientific Flexor Junior Analyzer.

**Comparison to Predicate device**

| | ELITech Clinical Systems Device (ELICAL 2) | Predicate device (Roche Calibrator f.a.s.) |
|---|---|---|
| Intended use | ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on Vital Scientific Selectra Junior Analyzer and Vital Scientific Flexor Junior Analyzer. | For *in vitro* diagnostic use in the calibration of quantitative Roche methods on Roche clinical chemistry analysers as specified in the value sheets. |
| Format | Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels | Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels |
| Level | Single level | Single level |
| Handling | Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam. | Carefully open one bottle, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam. |
| Traceability | Traceability information is given in the value sheet included in the box. | Traceability of the target value is given in the respective instruction for use of the system reagents. |
| Stability | Lyophilized:<br>To store at 2-8°C and protected from light until the expiry date<br><br>After reconstitution, the stabilities are :<br>- 8 hours between 15-25 °C.<br>- 2 days between 2-8 °C.<br>- 4 weeks between -25 and -15 °C (when frozen once) | Lyophilized:<br>Stable at 2-8°C up to expiration date.<br><br>After reconstitution, the stabilities* are :<br>- 8 hours at 15-25 °C.<br>- 2 days at 2-8 °C.<br>- 4 weeks at (-25)-(-15) °C (when frozen once)<br><br>*Exception for bilirubin total & direct as noted in package insert |

**Device names**

CONTROLS:

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| Trade/proprietary Name: | **ELITech Clinical Systems ELITROL I and ELITROL II** |
| Common or Usual Name: | Multi-analyte controls – all kinds, **"ELITROL I"- "ELITROL II"** |
| Device Class | Class I |
| Classification name | Quality control material (assayed and unassayed). (21 CFR 862.1660) |
| Product code | JJY- Multi-analyte controls – all kinds |

**Predicate device**

Roche Diagnostics Precinorm U (K041227)
Roche Diagnostics Precipath U (K041227)

**Device description**

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.
Elitrol I and Elitrol II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

**Intended Use**

ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on Vital Scientific Selectra Junior Analyzer and Vital Scientific Flexor Junior Analyzer.

**Comparison to Predicate device**

| | ELITech Clinical Systems Device<br>ELITROL I / ELITROL II | Predicate Device<br>Roche Precinorm U / Precipath U |
|---|---|---|
| Intended use | ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for in vitro diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on Vital Scientific Selectra Junior Analyzer and Vital Scientific Flexor Junior Analyzer. | For *in vitro* diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet |
| Format | Lyophilized human sera with constituents added as required to obtain desired components levels | Lyophilized human sera with constituents added as required to obtain desired components levels |
| Levels | Two levels | Two levels |
| Handling | Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam. | Carefully open the bottle, avoiding the loss of lyophilate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam. |
| Stability | Lyophilized:<br>To store at 2-8°C and protected from light until the expiry date<br><br>After reconstitution, the stabilities are :<br>- 12 hours between 15-25 °C.<br>- 5 days between 2-8 °C.<br>- 4 weeks between -25 and -15 °C (when frozen once) | Lyophilized:<br>Stable at 2-8°C up to expiration date.<br><br>After reconstitution, the stabilities* are :<br>- 12 hours at 15-25 °C.<br>- 5 days at 2-8 °C.<br>- 4 weeks at (-25)-(-15) °C (when frozen once)<br><br>*Exception for bilirubin total & direct as noted in package insert |

**Conclusion**

The performance data and other information demonstrate that the safety and effectiveness of these devices versus the predicate devices are not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Seppim S.A.S.
C/O Debra Hutson
Elitechgroup Epoch Biosciences
21720 23rd Dr, SE
Suite 150
Bothell, Washington 98021

NOV 18 2011

Re: k103376
Trade Name: Elitech Clinical Systems Creatinne PAP SL
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Codes: JFY, JJY, JIX
Dated: October 26, 2011
Received: October 27, 2011

Dear Ms. Hutson

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): _k103376 _____

Device Name: _____ELITech Clinical Systems CREATININE PAP SL _____

Indications for Use:

ELITech Clinical Systems CREATININE PAP SL is intended for the quantitative *in vitro* diagnostic determination of creatinine in human serum and plasma on Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

| | | |
|---|---|---|
| Prescription Use ___X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)__k103376_____

# Indications for Use Form

510(k) Number (if known): _k103376_____

Device Name: _____ ELITech Clinical Systems ELICAL 2_____

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for in vitro diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)__k103376_____

# Indications for Use Form

510(k) Number (if known): _k103376_____

Device Name: _____ ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I is a multi-parametric control serum for in vitro diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

ELITech Clinical Systems ELITROL II is a multi-parametric control serum for in vitro diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior analyzer and the Vital Scientific Flexor Junior analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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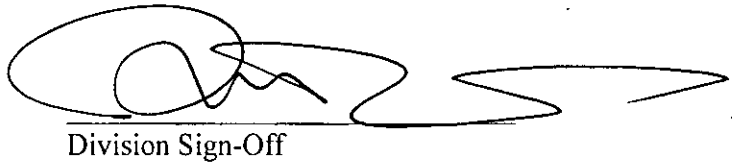
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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